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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,882	05/17/2006	Dominique Jean-Pierre Mabire	PRD-2124USPCT	8486
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PHILIP S. JOHNSON			EXAMINER	
JOHNSON & JOHNSON			BAEK, BONG-SOOK	
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NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER
			1614	
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			06/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/595,882	Applicant(s) MABIRE ET AL.
	Examiner BONG-SOOK BAEK	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 March 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6,8, and 10-28 is/are pending in the application.
- 4a) Of the above claim(s) 8,10-13 and 17-28 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6 and 14-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

Detailed Action

Status of claims

The amendment filed on March 16, 2010 is acknowledged. Claims 5, 7, 9, 29 and 30 have been canceled and claims 8, 10-13, and 17-28 have been withdrawn. Claims 1-4, 6, and 14-16 are under examination in the instant office action.

It is noted that the content of claim 29 is not deleted although the status of claim 29 is indicated as "(canceled)".

Applicants' arguments, filed on March 16, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various

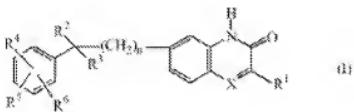
claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

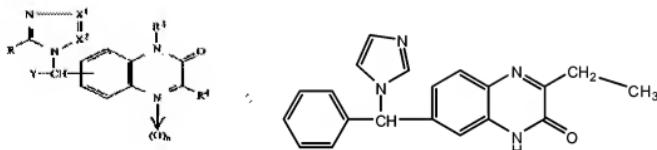
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,028,606.

The instant invention is drawn to a compound of the following formula (I) and a pharmaceutical composition comprising the compound of formula (I) and the following compound is recited in the instant claim 4. The elected species is free of prior art, thus examination is further extended the next species wherein X is N; n is 0; R¹ is C₁₋₆ alkyl; R² is hydrogen, R³ is a group of formula (b-1), t is 0 and Z is formula (c-2); and at least one of R⁴, R⁵ and R⁶ is other than hydrogen, halo, trihalomethyl, C₁₋₆ alkyl, or C₁₋₆ alkyloxy.



US patent 5,028,606 teaches substituted quinoxalinone derivatives (abstract and Table 9), wherein Y is Ar1, Ar2, hydrogen; C₁₋₁₀ alkyl; C₃₋₇ cycloalkyl; C₁₋₆ alkyl; C₂₋₆ alkenyl or C₂₋₆ alkynyl; and n is 0 or 1 and discloses the following compound (claim 1 and Table 9, compound 115):



It further teaches that the Ar2 is phenyl substituted with 1, 2 to 3 substituents each independently selected from halo, hydroxy, trifluoromethyl, C₁₋₆ alkyl, C₁₋₆ alkyloxy, cyano, amino, mono- and di(C₁₋₆ alkyl)amino, nitro, carboxyl, formyl and C₁₋₆ alkyloxycarbonyl (column 2, line 42-49 and claim 1).

The reference also teaches a pharmaceutical composition of substituted quinoxalinone derivatives with a pharmaceutically acceptable carrier (column 20, lines 47-58).

With regard to the instant claims 29, which are directed to a product made by the process of the instant claim 13, the reference discloses the same processes of making the substituted quinoxalinone derivatives as recited in the instant claim 13 (column 8, line 61-column 9, line 23 and column 10, lines 37-65). In the alternative, when the reference teaches a product that appears

to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process, either 102 or 103 rejection can be properly made. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP §2113. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The reference does not explicitly disclose a specific embodiment wherein the phenyl ring is substituted with a substituent other than hydrogen, halo, trihalomethyl, C₁₋₆ alkyl, or C₁₋₆ alkyloxy although the next species is a species of the genus disclosed in US patent 5,028,606, wheerein Y is phenyl substituted with hydroxy, cyano, amino, mono- and di(C₁₋₆ alkyl)amino, nitro, carboxyl, formyl and C₁₋₆ alkyloxy carbonyl; n is 0; and R4 is C₁₋₆ alkyl.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention was made to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie*

obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989). In addition, the reference already discloses the phenyl ring can be substituted with other than hydrogen, halo, trihalomethyl, C₁₋₆ alkyl, or C₁₋₆ alkyloxy such as hydroxy, cyano, amino, mono- and di(C₁₋₆ alkyl)amino, nitro, carboxyl, formyl and C₁₋₆ alkyloxycarbonyl. Thus, it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention was made to modify the compound of US patent 5,028,606 to arrive at the claimed compound by having the phenyl ring substituted with hydroxy, cyano, amino, mono- and di(C₁₋₆ alkyl)amino, nitro, carboxyl, formyl or C₁₋₆ alkyloxycarbonyl because such modifications have already been suggested by US patent 5,028,606.

Response to Applicant's argument

In response to the argument that the instant record fails to provide evidence as to whether the patent office considered Applicants' previous arguments, the previous arguments were fully considered, but they were moot in view of new grounds of rejection.

Applicant argued that '606 patent does not teach or suggest any degree of freedom for this modification as the Z substituent of the '606 patent is always directly bond to the carbon atom carrying the imidazolyl and there is no disclosure or suggestion in the '606 patent that an extra carbon atom may be inserted between the imidazolyl carrying carbon atom and the quinoxalinone moiety. This argument is irrelevant because the next species, which was examined in the last action, are compounds of formula (I) wherein X is N; n is 0; R¹ is C₁₋₆ alkyl; R² is hydrogen, R³ is a group of formula (b-1), t is 0 and Z is formula (c-2); and at least one of R⁴, R⁵ and R⁶ is other than hydrogen, halo, trihalomethyl, C₁₋₆ alkyl, or C₁₋₆ alkyloxy, thus the

compounds do not have extra carbon atom between the imidazolyl carrying carbon atom and the quinoxalinone moiety. The only difference is that the reference does not explicitly disclose the specific embodiment of such species although the next species embraced by the genus disclosed in US patent 5,028,606 when Y is phenyl substituted with di(C₁₋₆ alkyl)amino and C₁₋₆ alkyloxycarbonyl; n is 0; and R4 is C₁₋₆ alkyl. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

In response to the argument that the claimed compounds have PARP inhibiting activity, which is different from that of the compounds of '606 patent, it is noted that the features upon which applicant relies (i.e., having PARP inhibiting activity) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It appears that the above rejection may be overcome by amending the claim to carve out species, which are embraced by '606 patent.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

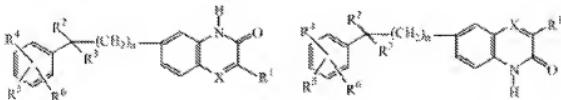
application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

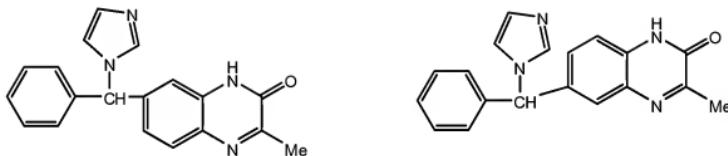
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, and 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 7 of copending Application No. 10/595,891 in view of US 5,028,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to substituted quinolinone and quinoxaline compounds of the almost identical structure and the same substitutions. The difference between the instant compounds and the compounds of the

*891 application is the position of the substitution (position 7 for the instant application and position 6 for the *891 application) as shown below:



As stated in the first 102 rejection above, US 5,028,606 teaches the same compounds as the instant invention. It further shows that position isomers, which have a substitution in the either position 6 or position 7 of quinoxaline ring, are possible while retaining the same biological activity. The following is an example of positional isomers shown in US 5,028,606.



It would have been obvious to a person of ordinary skill in the art at the time the invention was made to change substitution position to get another positional isomer with a reasonable expectation of success. MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). In addition, US 5,028,606 already suggests making positional isomers of the same core structure as the instant invention in the same positions while

retaining the same biological activity. One skilled in the art would have been motivated to prepare positional isomers as taught by the prior art with the expectation of obtaining another homologous compound which will retain the same activity.

This is a provisional obviousness-type double patenting rejection.

Since a terminal disclaimer has not been filed and no argument was presented, the above double patenting rejection is properly maintained.

Examiner's note

Claims 2-4 and 14-16 would be allowable if the above double patenting rejection is overcome by filing a terminal disclaimer.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
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